REMARKS

Claims 14-18, 23-30 and 32-62 are pending in this application.

Claims 16-18, 30 and 32-48 have been previously withdrawn from consideration.

Claims 1-13, 15, 19-22, 26, 28, 29 and 31 have been canceled, without prejudice.

Claims 14, 15, 23-29 and 49-62 stand rejected.

Claims 14, 23-25, 27, 49, 50, 55, 56, and 59-62 have been amended. Support for these amendments can be found throughout the specification, as originally filed.

35 USC §112, SECOND PARAGRAPH REJECTION

Claims 49-62 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Applicant respectfully traverses the 35 U.S.C. §112, second paragraph, rejection of claims 49-62.

In the interests of expediting prosecution of the instant application, and without admission that any amendment is required, the Applicant has amended claims 49, 55 and 61 to recite, among other things, an adrenergic bronchodilator component. The examiner improperly inferred that the recitation of an adrenergic bronchodilator implied a single chemical compound. This was clearly not the intent of the Applicant, as the specification is replete with references to albuterol (i.e., an adrenergic bronchodilator) being simultaneously present (i.e., in a therapeutic composition) in an immediate release form and an extended release form. As the Examiner is no doubt aware, time release compositions are well known in the art. Thus, one of ordinary skill in the art would easily recognize that the claimed adrenergic bronchodilator included both an

immediate release form and an extended release form.

Accordingly, the Applicant submits that the 35 U.S.C. §112, second paragraph, rejection of claims 49-62 has been overcome or rendered moot.

35 USC §103(a) REJECTION

Claims 14, 15, 23-29 and 49-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Dahlen et al. (WO 97/28797) in view of Katzung ("Basic & Clinical Pharamacology", 6th ed., 1995, page 312-314), and Spector et al. (J. Allergy Clin. Immunol., 1995; 96(2): 174-181).

The Applicant respectfully traverses the 35 U.S.C. §103(a) rejection of claims 14, 15, 23-29 and 49-62. Claim 15 has been canceled, without prejudice, and the subject matter thereof substantially incorporated into independent claim 14.

The standard for obviousness is that there must be some suggestion, either in the reference or in the relevant art, of how to modify what is disclosed to arrive at the claimed invention. In addition, "[s]omething in the prior art as a whole must suggest the desirability and, thus, the obviousness, of making" the modification to the art suggested by the Examiner. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 U.S.P.Q.2d (BNA) 1434, 1438 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988). Although the Examiner may suggest the teachings of a primary reference could be modified to arrive at the claimed subject matter, the modification is not obvious unless the prior art also suggests the desirability of such modification. *In re Laskowski*, 871 F.2d 115, 117, 10 U.S.P.Q.2d (BNA) 1397, 1398 (Fed. Cir.1989). There must be a teaching in the prior art for the proposed combination or modification to be proper. *In re Newell*, 891 F.2d 899, 13 U.S.P.Q.2d (BNA) 1248 (Fed. Cir. 1989). If the prior art fails to

provide this necessary teaching, suggestion, or incentive supporting the Examiner's suggested modification, the rejection based upon this suggested modification is error and must be reversed. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d (BNA) 1566 (Fed. Cir. 1990).

The law is also clear that a claim in dependent form shall be construed to incorporate all the limitations of the claim to which it refers. 35 U.S.C. 112, fourth paragraph.

In the interests of expediting prosecution of the instant application, and without admission that any amendment is required, the Applicant has amended claim 14 to recite, among other things, a composition for the treatment of asthma, the composition comprising: (1) a montelukast sodium component; (2) an antihistamine component selected from the group consisting of cetirizine, fexofenadine, and combinations thereof; and (3) a sympathomimetic bronchodilator component, wherein said sympathomimetic bronchodilator component is albuterol, wherein said albuterol includes an immediate release form and an extended release form, wherein said immediate release form is present in an amount substantially equal to said extended release form.

In the interests of expediting prosecution of the instant application, and without admission that any amendment is required, the Applicant has amended claim 23 to recite, among other things, a composition for the treatment of asthma, the composition comprising: (a) a leukotriene receptor antagonist component; (b) a histamine receptor antagonist component selected from the group consisting of cetirizine hydrochloride, fexofenadine, and combinations thereof; and (c) an adrenergic bronchodilator component, wherein said adrenergic bronchodilator component includes an immediate release form and an extended release form wherein, said immediate release form is present in an amount substantially equal to said extended release form.

In the interests of expediting prosecution of the instant application, and without admission that any amendment is required, the Applicant has amended claim 49 to recite, among other things, a composition for the treatment of asthma, the composition comprising: (1) a first receptor antagonist component and a second receptor antagonist component, said first and second receptor antagonist components being independently selected from the group consisting of leukotriene receptor antagonists, histamine receptor antagonists, and combinations thereof; and (2) an adrenergic bronchodilator component, the adrenergic bronchodilator component including an immediate release form and an extended release form, wherein said immediate release form is present in an amount substantially equal to said extended release form.

In the interests of expediting prosecution of the instant application, and without admission that any amendment is required, the Applicant has amended claim 55 to recite, among other things, a composition for treatment of asthma, the composition comprising: (1) a first receptor antagonist component comprising a leukotriene receptor antagonist; (2) a second receptor antagonist component comprising a histamine receptor antagonist; and (3) an adrenergic bronchodilator component, the adrenergic bronchodilator component including an immediate release form and an extended release form, wherein said immediate release form is present in an amount substantially equal to said extended release form.

In the interests of expediting prosecution of the instant application, and without admission that any amendment is required, the Applicant has amended claim 61 to recite, among other things, a composition for the treatment of asthma, the composition comprising: (1) a montelukast sodium component; (2) an antihistamine component selected from the group consisting of cetirizine, loratadine, fexofenadine, and combinations thereof; and (3) an adrenergic bronchodilator component, the adrenergic bronchodilator component including an

immediate release form and an extended release form, wherein said immediate release form is present in an amount substantially equal to said extended release form.

Neither Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, disclose or suggest the invention as claimed in any of independent claims 14, 23, 49, 55 and 61, as amended, or the claims dependent therefrom.

Specifically, neither Dahlen et al., Katzung, and/or Spector et al., disclose or suggest the use of an adrenergic bronchodilator component that includes an immediate release form and an extended release form. Furthermore, neither Dahlen et al., Katzung, and/or Spector et al., disclose or suggest the use of an adrenergic bronchodilator component that includes an immediate release form and an extended release form, wherein the immediate release form is present in an amount substantially equal to the extended release form. As the Examiner correctly noted, Dahlen et al. is completely silent on the use of andrenergic bronchodilators. While Katzung arguably discloses the use of albuterol, this is not the same as disclosing an adrenergic bronchodilator component that includes both an immediate release form and an extended release form. Furthermore, Katzung certainly does not disclose that the immediate release form is present in an amount substantially equal to the extended release form. The recitation of Spector et al. does not cure the deficiencies in the disclosures of either Dahlen et al. and/or Katzung. Accordingly, one or ordinary skill in the art would rightfully conclude that none of these references were concerned with the problem of nighttime onsets of asthma attacks and the solution provided by the instant invention, that is the combination of the recited components of the present invention, but more importantly, the use of an adrenergic bronchodilator which provided both immediate release medication and extended release medication to prevent or at least lessen the severity/incidence of nighttime asthma attacks. For example, see the clinical

evidence of the efficacy of the compositions of the present invention, including reduced nighttime asthma attacks, set forth in the specification at Paragraphs [0045]-[0054]. Thus, one of ordinary skill in the art would not look to Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for guidance on a composition for treatment of asthma, as presently claimed.

Thus, neither Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, renders independent claims 14, 23, 49, 55 and 61 obvious. Because claim 23 is allowable over Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for at least the reasons stated above, claims 24, 25 and 27, which depend from and further define independent claim 23, are likewise allowable. Because claim 49 is allowable over Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for at least the reasons stated above, claims 50-54, which depend from and further define independent claim 49, are likewise allowable. Because claim 55 is allowable over Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for at least the reasons stated above, claims 56-60, which depend from and further define independent claim 55, are likewise allowable. Because claim 61 is allowable over Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for at least the reasons stated above, claim 62, which depends from and further defines independent claim 61, is likewise allowable.

CONCLUSION

In view of the foregoing, the Applicant respectfully requests reconsideration and reexamination of the Application. The Applicant respectfully submits that each of the claims in this Application is in condition for allowance and such allowance is earnestly solicited.

Examiner is invited to telephone the Applicant's undersigned attorney at (248) 723-0487 if any unresolved matters remain.

Any needed extension of time is hereby requested with the filing of this document.

The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 08-2789.

Respectfully submitted,

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